

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

6300.1

10/9/14

MANUFACTURE OF ANIMAL FOOD OR UNINSPECTED ARTICLES AT OFFICIAL ESTABLISHMENTS

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) regarding their responsibilities in an official establishment that manufactures animal food or similar uninspected articles in the edible product department.

KEY POINTS:

- Provides instructions to IPP on what they are to do when an official establishment prepares animal food or similar uninspected articles not for human consumption in the edible department*
- Provides instructions to IPP on what they are to do when inedible products enter the edible product department for the manufacture of animal food or uninspected articles*
- Provides information on when the requirements in [9 CFR 318.12](#) and [381.152](#) do not apply, such as when an establishment conducts irradiation or High Pressure Processing (HPP) of sealed packaged pet food*

II. BACKGROUND

[9 CFR 318.12](#) and [381.152](#) outline the regulatory requirements for manufacturing animal food or uninspected articles in an official establishment. These regulations permit the preparation of animal food or other uninspected meat, meat food, poultry, or poultry products in the edible and inedible departments of official establishments. Inedible or uninspected ingredients may be assembled or further processed into retail ready pet food products or as an ingredient in a product to be further processed by a pet food manufacturer in accordance with [9 CFR 318.12](#) and [381.152](#).

III. IPP RESPONSIBILITIES IN ESTABLISHMENTS SUBJECT TO 9 CFR 318.12 and 381.152

A. IPP are to verify that establishments comply with [9 CFR 318.12\(a\)](#) or [381.152\(a\)](#) by using the PHIS Sanitation Performance Standards (SPS) Verification task and by following the instructions in [FSIS Directive 5000.1](#), *Verifying an Establishment's Food Safety System*, Chapter II, Part I and II.

B. IPP are to use the following questions to determine whether inedible and uninspected products are being properly handled in the edible product department of the establishment:

NOTE: IPP will verify [9 CFR 318.1\(a\)](#) in official meat establishments and [9 CFR 381.145\(a\)](#) in official poultry establishments on what products may enter the establishments.

1. Does the official establishment have adequate facilities to ensure that the carcasses or parts are saved under [9 CFR 310.16\(c\)](#), [314.10](#), [314.11](#), or [381.152\(a\)](#), and other inedible products are prepared in a sanitary manner, i.e., facilities are adequate to ensure that only materials without pus, manure, diseased, septic, or toxic materials, or similar substances enter any edible product department?

NOTE: The requirements in 9 CFR 318.12(b) do not allow dead animals, condemned products, or similar materials of whatever origin, to be used in edible areas.

2. Is the manufacturing of uninspected products, such as animal food, in the edible product departments limited to the establishment's approved hours of operation?
3. Does the establishment have adequate facilities to maintain sanitary conditions if animal food is stored in the edible product department?
4. Is the animal food or uninspected product properly identified as required by [9 CFR 318.12\(c\)](#), [325.11\(d\)](#), [381.152\(c\)](#), or [381.193\(b\)](#)?

NOTE: The brains and spinal cords from cattle 30 months of age and older (i.e., Specified Risk Material (SRM)) are to be removed from any carcasses and parts used for preparation of animal food as required by [21 CFR 589.2001](#) of the Food and Drug Administration (FDA) regulations implementing the feed ban rule.

C. IPP are to document any non-compliance as set out in Chapter II of [FSIS Directive 5000.1](#).

D. IPP are to take a regulatory control action to stop the use of the equipment when the manufacturing of uninspected animal food:

1. Results in the creation of insanitary conditions;
2. Adulterates inspected product;
3. Interferes with the preparation of the inspected product, or
4. Interferes with inspection.

E. If any of the situations described in paragraph D., above, occurs, IPP are to verify that the establishment provides separate equipment for the uninspected articles in accordance with [9 CFR 318.12\(a\)](#) or [381.152\(a\)](#).

IV. IPP RESPONSABILITIES IN ESTABLISHMENTS NOT SUBJECT TO 9 CFR 318.12 AND 381.152

The regulatory requirements in [9 CFR 318.12](#) and [381.152](#) do not apply to irradiation or HPP of animal food or similar uninspected articles not intended for human consumption provided that IPP verify that the establishment does the following:

1. Ensures that no manufacturing or preparation of animal food or other articles not intended for human food occurs as discussed in 9 CFR [318.12](#) or [381.152](#). Under these regulations, "manufacturing" or "preparation" includes product formulation or physical handling of exposed raw materials; and
2. Has procedures in its Sanitation SOP that address how it will ensure compliance with [9 CFR 416.12](#) when changing operation from uninspected articles processing to processing of inspected meat, poultry, or egg products. For example, the Sanitation SOP program has a written program to identify, control, and segregate the uninspected articles from inspected articles to include:
 - a. Distinguishing the animal food from articles of human food in accordance with 9 CFR [318.12\(c\)](#); and
 - b. Distinguishing the animal food from human food in accordance with 9 CFR [381.193\(b\)](#).

3. Handles only sealed final-packaged inspected and uninspected articles that are not opened or exposed to the environment;

NOTE: This assumes leakers that occur in HPP are destroyed.

4. Do not conduct irradiation or HPP of sealed animal food or similar uninspected articles not intended for human consumption during regular hours of inspection; and

NOTE: When the requirements in [9 CFR 318.12\(c\)](#) and [381.193\(b\)](#) are met, the establishment may bring uninspected animal food and inedible product not intended for human consumption into the official establishment in accordance with [9 CFR 318.1\(a\)](#) and [381.145\(a\)](#).

5. Complies with all FDA requirements when irradiating animal food or similar USDA FSIS uninspected articles not intended for human consumption. These requirements include but are not limited to the requirement for irradiation in the production, processing, and handling of animal feed and pet food in [21 CFR Part 579](#) and the requirement to register the facility with FDA in [21 CFR 1.227](#). Additionally, the establishment is required to comply with the federal, state, or local regulatory requirements that apply to the irradiation of animal food or similar uninspected articles not intended for human consumption.

V. QUESTIONS

Refer questions regarding this directive to the Policy Development Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 6300.1**

Question Field: Enter your question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.

Category Field: Select **Regulations/Agency Issuance** from the drop-down menu.

Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: For additional information regarding how to submit a question in askFSIS, IPP are to refer to [FSIS Directive 5620.1](#), *Using askFSIS*.



Assistant Administrator
Office of Policy and Program Development